

JUDGE PATTERSON

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

10 CIV 1113

ROCHE MOLECULAR SYSTEMS, INC.

Plaintiff,

vs.

DXS LIMITED,

Defendant.

Case No.

COMPLAINT
Jury Trial Demanded 2010

U.S.D.C. S.D. N.Y.
CASHIERS

Plaintiff Roche Molecular Systems, Inc. ("Roche"), as and for its Complaint
against Defendant DxS Limited ("DxS") alleges as follows:

NATURE OF THE CLAIMS

1. This case involves the sale of diagnostic testing products in an emerging and rapidly evolving field of medicine known as "personalized healthcare." In the past, doctors' understanding of a patient's particular susceptibility to diseases, as well as his or her individual responses to therapies, has been largely based on signs and symptoms that can be seen and felt. Until recently, doctors have not had access to the underlying biological processes that start with the genetic sequence. With the advent of "personalized healthcare" that has changed, and revolutionary technologies are now beginning to become commercialized that permit new diagnostic precision.

2. Advances in the understanding of genetics, coupled with sophisticated molecular assays, now allow physicians to diagnose and tailor the treatment of a disease on an individualized basis, based on a person's genetic makeup, rather than in a

generalized manner. The development of molecular assays allows physicians to determine which pharmaceuticals and courses of treatment will work best with each individual patient's genetic profile. As a result, research into personalized healthcare is expanding as a method to develop treatments of cancer tailored to an individual patient's genetic needs.

3. Until recently, Defendant DxS was a small and pioneering molecular diagnostics company that designed, developed, manufactured and sold diagnostic tests, or "assays" used to predict drug response in the field of cancer and other diseases. DxS works in partnership with pharmaceutical companies to develop companion diagnostics to support the prescription of the drug therapies for patients most likely to benefit.

4. Among the products in its portfolio are diagnostic kits that detect mutations or deletions in two genes associated with cancer, called K-RAS and EGFR. K-RAS and EGFR have been shown to be "biomarkers" associated with colorectal and lung cancer, respectively, that is, mutations in those genes are linked to the development of those cancers.¹ The particular mutation or deletion present in a tumor can dictate which treatments will be most effective, and thus identification of mutations or deletions in a patient will lead to better treatments. DxS's K-RAS and EGFR assays, sold under the TheraScreen® brand name, do just that by providing the ingredients necessary to analyze a tumor-tissue DNA sample and identify mutations in it.

5. Plaintiff Roche also develops diagnostic assays. In recent years, it has invested in developing proprietary assays for the detection and amplification of DNA in

¹ A biomarker is biological material, such as protein or DNA, that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

several viral and bacterial pathogens, including tuberculosis, human immunodeficiency virus (HIV), and human papillomavirus (HPV). Roche also manufactures and markets diagnostic platforms and systems for performing real-time, automated DNA analysis, such as the COBAS® and LightCycler® molecular diagnostic platforms.

6. Like other diagnostic companies, Roche had been, and remains, eager to enter into and expand its presence in the field of personalized healthcare in the market's early stages. In December 2007, DxS approached Roche about entering into an exclusive distributor relationship, a unique opportunity that would enable Roche to gain a presence in the emerging and dynamic market of personalized healthcare for cancer diagnostics. The parties began negotiations soon thereafter.

7. In May 2008, Roche and DxS had completed negotiations and entered a distribution agreement (the "Distributor Agreement"). As noted on its website, the Distributor Agreement gave DxS the benefit of Roche's global distribution network: "DxS has a global distribution partner – Roche Diagnostics – to guarantee that the test is available for sale and supported in all relevant markets, leveraging Roche Diagnostics distribution channels with direct operations in 76 countries." Attached as Exhibit A is a copy of the relevant web page from DxS's website.

8. Both parties substantially performed their respective obligations under the Distributor Agreement for more than sixteen months. Through this relationship Roche was building its reputation as a reliable source for these groundbreaking assays in the field of personalized medicine.

9. In September 2009, DxS was acquired by a company called Qiagen N.V., a much larger Dutch company that is publicly traded in Europe and the United States.

The transaction was valued at approximately \$95 million in cash, plus up to an additional \$35 million if specified commercial and other milestones are met. Attached as Exhibit B is a copy of a Qiagen press release, dated September 22, 2009.

10. Shortly after DxS was acquired by Qiagen, DxS began accusing Roche of breaching the Distributor Agreement. Despite Roche's repeated denials of the accusations and requests of DxS to provide additional facts on which its allegations are based, the accusations simply continued and have now escalated to the point that DxS has said that it will terminate the Distributor Agreement on February 15, 2010.

11. DxS has no basis to terminate the Distributor Agreement. While DxS claims that Roche failed to assist DxS in the development of software, this is a pretext because Roche had no such obligation under the Distributor Agreement. Rather, by its terms the Distributor Agreement was a distribution contract of specified Products manufactured by DxS. In short, the "failure" by Roche to develop software is not a violation of the Distributor Agreement and cannot be the basis of a valid termination. DxS's threat to terminate the Distributor Agreement without cause is an anticipatory breach and a breach of the implied covenant of good faith and fair dealing. DxS continued with the Distributor Agreement for as long as it was convenient to do so, and now seeks to terminate it unless Roche agrees to new business terms outside the scope of the Distributor Agreement.

12. Termination of the Distributor Agreement will cause immediate, irreparable injury to Roche. The field of personalized medicine, and especially cancer diagnostics, is an emerging market, and pharmaceutical and medical device companies are currently staking out relative positions within it. The next few years are a critical

period for Roche to establish its place in this market, gain credibility and momentum, and develop a reputation for reliability and quality (as Roche has done in other areas). As DxS is at the forefront of the field of DNA-based oncological diagnostic assays, Roche's place as DxS's exclusive distributor for these Products is a unique and invaluable opportunity. If DxS wrongfully terminates the Distributor Agreement, Roche will suffer irreparable harm and jeopardize its ability to establish itself as a major player in this new market. DxS's products are proprietary assays for which there are no comparable substitutes. Roche lacks its own proprietary tests and it will take years for such tests to be brought to market. Simply put, exclusive distribution rights to the K-RAS and EGFR tests provide Roche with a competitive advantage that cannot be recovered if the Distributor Agreement is wrongfully terminated.

PARTIES

13. Roche Molecular Systems, Inc. is a Delaware corporation, and is an affiliate of F. Hoffmann-La Roche Ltd, and maintains a place of business at 4300 Hacienda Drive, Pleasanton, California 94588.

14. Upon information and belief, DxS Limited is a United Kingdom corporation with its principal place of business in Manchester, England.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction pursuant 28 U.S.C. § 1332 because Roche is a citizen of a State and DxS is a citizen of a foreign state, and the amount in controversy exceeds \$75,000.

16. This Court has personal jurisdiction over DxS because Paragraph 15 of the Distributor Agreement provides that "any legal proceeding with respect to or arising

under" the Distributor Agreement shall be "exclusively brought" in New York. Ex. A, ¶ 15.

17. Venue is proper pursuant to 28 U.S.C. § 1391 (a) and (d) because the Distributor Agreement provides that venue is proper in this district and because Defendant is a resident of a foreign state.

FACTS

Personalized Healthcare and Molecular Diagnostics is an Emerging and Highly Lucrative Market

18. Personalized healthcare is based on the observation that patients with the same diagnosis react to the same treatment in different ways: while a drug can be highly effective for one patient, the same drug might not show the desired results when given to a second patient with the same diagnosis. A patient's individual characteristics, as well as certain environmental factors (i.e., smoker v. non-smoker), influence the way drugs work; treating all patients diagnosed with a certain disease with a broad-brush approach disregards those differences. In other words, conventionally practiced healthcare is not as effective as it could be, with a considerable number of patients receiving treatments that are inappropriate for them, including treatments that could cause adverse reactions in some cases. Personalized healthcare has the potential to reduce or eliminate the use of treatments that are ineffective or dangerous in pre-defined patient populations. It is an approach that capitalizes on the increasingly sophisticated understanding of differences among patients, the molecular basis of disease and of how medicines work.

19. New developments in molecular diagnostics, particularly in the tissue-based cancer diagnostics area, are key to personalized healthcare because they provide

doctors with specific information about clinically relevant aspects of disease, enabling more targeted treatment for each patient. The advances in technologies and techniques that make molecular diagnostics possible, such as rapid and real-time analysis of DNA, have only recently become commercially viable. It is no surprise then that the molecular diagnostics market is developing rapidly. In the past six years, for example, the global market for molecular diagnostic products has doubled from \$1.8 billion in 2004 to \$3.6 billion in 2009, and it is projected to double again to approximately \$7 billion by 2015.

20. Cancer diagnostics is the key area for growth and innovation because of the significant research conducted in this field. Generally, clinicians categorize cancer cells according to their pathology, i.e. their appearance under a microscope. Molecular diagnostic tools permit the clinician to differentiate between cancer cells that appear to have the same pathology by analyzing and comparing the DNA. This approach allows physicians to target treatment to a particular patient's molecular tumor type. Given the obvious benefits of more targeted and efficacious cancer treatment and the dearth of diagnostic tools to differentiate between various cancer types, pharmaceutical and medical device companies are investing heavily in the market for cancer diagnostics.

*Roche is Seeking and Developing Opportunities
in the Molecular Diagnostics Market*

21. Roche is the world leader in the field of molecular diagnostics, offering tests that utilize the Polymerase Chain Reaction ("PCR") technology for which Kary Mullis won the Nobel Prize in Chemistry in 1993. Roche's blood screening tests are used to identify infections such as HIV and hepatitis in donated blood, plasma, and organs, helping to reduce transmission of these serious diseases during transfusions,

transplantations, or administration of other medical therapies derived from such products. Roche also manufactures and markets diagnostic testing platforms and systems for performing real-time, automated DNA analysis, such as COBAS® the LightCycler® molecular diagnostic platforms.

22. Roche has an extensive distribution network throughout the world that includes distribution channels with operations in more than 75 countries.

DxS Was a Start-Up that Developed Pioneering Cancer Diagnostic Assays

23. DxS is a developer and manufacturer of molecular diagnostic assays used in personalized medicine for oncology. Among the products in its portfolio are diagnostic kits that detect mutations or deletions the K-RAS or EGFR genes in tumors. K-RAS and EGFR have been shown to be “biomarkers” associated with colorectal and lung cancer, respectively, that is, mutations in those genes are linked to the development of those cancers. Mutations in those genes can, among other things, indicate a patient’s likely response to oncology drugs, enabling physicians to better treat a patient by selecting the drug most likely to work for the patient. DxS’s K-RAS and EGFR assays, sold under the TheraScreen® brand name identify those mutations.

24. DxS’s TheraScreen® K-RAS Mutation Test (the “K-RAS test”) was one of the first clinically validated, CE-Marked companion diagnostics to identify K-RAS mutations or deletions in colorectal cancer. The test detects seven frequent mutations in the K-RAS gene that are frequently found in multiple cancer types, including colorectal cancer, pancreatic cancer, lung adenocarcinoma, gall bladder cancer, bile duct cancer and thyroid cancer.

25. DxS's TheraScreen[®] EGFR-29 Test (the "EGFR test") detects different mutations or deletions in the EGFR gene that are commonly found in non-small cell lung cancer. Like K-RAS, those mutations or deletions can inform which treatments will be most effective.

26. Roche currently does not have a proprietary product to detect K-RAS or EGFR mutations. In addition, EGFR testing is covered by patents to which Roche does not have a license. No other comparable EGFR or K-RAS tests are on the market.

The Parties Entered into an Exclusive Distributor Agreement

27. Unlike Roche, DxS was a small, start-up company with limited distribution channels. Unlike DxS, Roche did not sell any products that were equivalent to DxS's tests. Recognizing that having these DxS assays in its portfolio of offerings would provide Roche with an important competitive advantage in personalized medicine generally, and specifically in cancer diagnostics, by allowing Roche to be first to market with such tests. As a result, Roche was interested when DxS approached it to enter into a mutually beneficial distribution agreement whereby they each could draw on the other's strengths for a fixed period of time.

28. The Distributor Agreement, which contains an integration clause, contains no provision requiring Roche to research, develop, or manufacture any products itself, or in collaboration with DxS, nor does it contain any provisions relating to software.

29. The DxS K-RAS and EGFR assays consist of reagents that are combined with DNA isolated from a tumor-tissue sample and placed into a separate, stand-alone machine, known as a "platform," which may be capable of performing several different functions, including DNA analysis. The platform then analyzes the DNA sample and

provides the clinician with information and data indicative of whether there are mutations and deletions in the K-RAS and EGFR genes. The DxS K-RAS and EGFR assays can be run on a platform manufactured by Applied Biosystems, Inc. ("ABI") or on the Roche LightCycler® 480 Instrument II platform.

30. During the first approximately year and a half of the Distributor Agreement, both sides substantially performed their respective obligations under the Distributor Agreement, with Roche laying the foundation for DxS to establish a strong distribution network for the Products and assisting DxS in bringing those Products to market. Among the efforts taken by Roche to promote, market and sell the DxS products was training its affiliates on how to use and support the assays and promoting the tests through symposia, including an international symposium in Stockholm.

31. Each time the parties recognized that an issue was not encompassed within the Distributor Agreement, they negotiated a separate agreement to address the issue. For example, when DxS sought access to certain Roche proprietary software to enable the K-RAS Product to perform better on the Roche platform, the parties negotiated a Software License Agreement, effective in January 2009, by which Roche licensed the software to DxS. The parties later amended that agreement to specify the territories in which DxS could distribute the software. Likewise, in late 2008, when it became clear that DxS lacked the required experience and expertise in the regulatory and quality arenas to fulfill its contractual obligations, the parties negotiated an amendment to the Distributor Agreement ("Amendment") that stated Roche would provide assistance to DxS in the above areas at DxS's cost.

32. As part of the Amendment, Roche helped to refine the Products' labeling and package inserts, lent regulatory support and aided DxS when it faced quality issues, and provided registration assistance in foreign countries. By the same token, Roche, by virtue of the Distributor Agreement, was able to expand its profile in the field of oncological molecular diagnostics. Overall, this mutually beneficial relationship provided both companies with positive results in the marketplace.

33. In the spring of 2009, as a result of the parties' discussions regarding the future distribution of products on multiple platforms, the parties recognized that a great degree of effort would be necessary to develop new software to automate the use of DxS's products on additional platforms, including Roche's proprietary testing and FDA-compliant platform known as COBAS® 4800. Understanding that the Distributor Agreement did not contain any provisions regarding software development and that any software development would require Roche to disclose proprietary information and undertake significant expenditures, the parties began negotiating a Master Software Development and License Agreement ("Master Software Development Agreement") that would govern the terms, conditions and consideration for any development of software for the DxS products.

34. Throughout the spring and summer of 2009, the parties had extensive discussions about possible terms and conditions of the Master Software Development Agreement, which included the involvement of DxS's outside counsel. Roche provided numerous revised drafts of the Master Software Development Agreement to DxS during this time, with extended periods of time passing before Roche received any response on its proposed changes from DxS.

35. In August 2009, Roche learned that DxS was in discussions regarding a potential acquisition with a third-party. Because DxS had delayed the negotiation on the Master Software Development Agreement and because Roche decided to wait until DxS's activities with the potential third-party acquirer were complete, Roche notified DxS on September 2, 2009 that it was ceasing any further negotiations on the Master Software Development Agreement.

36. The parties exchanged correspondence on September 4, 2009, in which Roche stated that it was willing to revisit the issue of the Master Software Development Agreement after DxS's discussions with the third-party were concluded.

37. On September 22, 2009, Roche learned that DxS was purchased by Qiagen N.V., one of Roche's main competitors.

38. No meeting of the minds was ever reached on the draft Master Software Development Agreement and no agreement was ever signed.

*Qiagen's Acquisition of DxS Affects
DxS's Willingness to Perform Under the Distributor Agreement*

39. Unlike DxS, Qiagen is a publicly-traded company, on NASDAQ and the Frankfurt Prime Standard, with over 400,000 customers worldwide from academia, pharma diagnostics and the biotech industry. Qiagen touts itself as the "world's leading provider for innovative sample and assay technologies for research in molecular diagnostics, applied testing, pharma and academic research" and claims that it "offers more molecular diagnostic sample and assay technologies than any other company." Qiagen owns over 1,500 U.S. patents, and manufactures and sells over 500 products. In 2008, Qiagen's net sales were \$893 million, and its stock has steadily increased over the past year.

40. Qiagen markets a wide variety of molecular diagnostic tools. In its 2008 Annual Report, Qiagen identified Roche as one of its main competitors in every segment of the molecular diagnostic market. In fact, Roche and Qiagen are competitors and both share the goal of taking a strong leadership position in the new era of personalized healthcare.

41. In announcing the acquisition of DxS in a September 22, 2009 press release, Qiagen emphasized the emerging nature of the market for molecular diagnostic assays, and DxS's special position in that market:

DxS has developed a set of molecular diagnostic assays which allow physicians in oncology to predict patients' responses to certain treatments in order to make cancer therapies more effective and safer. The currently marketed portfolio spans seven real-time PCR tests including a test for the mutation status of the oncogene K-RAS, which is indicative for successful treatment of patients suffering from metastatic colorectal cancer (mCRC) with EGFR inhibitors. In addition, three assays are in the near-term pipeline and further assays are in the medium-term pipeline. DxS' portfolio of assays, both marketed and in its pipeline, is strongly suitable for use with QIAGEN's existing suite of platform instruments, including QIASymphony and Rotor-Gene Q.

DxS is one of the pioneers which have brought molecular companion diagnostics to market. The TheraScreen: K-RAS Mutation Kit® developed by DxS has already been CE-marked. In the United States, the test is expected to be submitted to the FDA for regulatory approval (PMA) in 2010. It is estimated that in the future the market for overall K-RAS testing could reach up to \$100 million. DxS' current portfolio and near-term pipeline includes ten unique and proprietary assays. The company has accumulated a significant intellectual property portfolio for its current and planned diagnostic content.

42. While the relationship between Roche and DxS had been working for both parties, once Qiagen entered the scene everything changed dramatically. The next communication Roche received from DxS after the September 4, 2009 exchange was on October 12, 2009. Instead of requesting that the negotiations on the draft Master Software Development Agreement continue, on that date DxS purported to notify Roche that Roche had allegedly breached the Distributor Agreement. While knowing the draft Master Software Development Agreement was never completed, fully negotiated, or signed, DxS asserted that Roche had agreed to collaborate with DxS to develop software for DxS's products to run on Roche's COBAS® 4800 system. In later correspondence, DxS contended that Roche's conduct also violated the covenant of good faith and fair dealing. Roche denied the allegations, but as a result, negotiations on the Master Software Development Agreement were not resumed. Nonetheless, Roche continued to perform its obligations under the Distributor Agreement.

43. DxS's allegations are unfounded. The contract between the parties is a distributor agreement, not a collaboration agreement or a manufacturing agreement. The Distributor Agreement sets forth Roche's obligations to promote, market and sell the Products only. Nowhere in the Distributor Agreement is Roche obligated to develop products, it just needs to market and sell them. With respect to software specifically, the parties recognized that the development of software to make the DxS products compatible with Roche's platforms was not included in the Distributor Agreement as reflected by the fact that (1) a limited Software License Agreement was necessary for DxS to use the LightCycler® Adapt software together with its TheraScreen® K-RAS Product, and (2) the parties were in the midst of negotiating a separate agreement for

the development of software to support multiple products on multiple platforms. Given the slow turnaround time for the draft Master Software Development Agreement, and the fact that DxS was preparing itself to be acquired by a main competitor, Roche decided to forego further negotiations on the Master Software Development Agreement, but that did not vitiate in any way both sides' rights and obligations under the Distributor Agreement.

44. Upon information and belief, DxS is seeking to avoid its exclusive obligations with Roche because it no longer finds it advantageous to benefit from the Roche distribution network. Clearly, it would rather use the distribution network of its new corporate parent Qiagen. However, DxS has no basis to terminate the relationship because Roche has fully performed its obligations under the Distributor Agreement.

45. Since culminating its deal with Qiagen, DxS has failed to perform its obligations under the Distributor Agreement. Specifically, DxS is currently unable to meet Roche's needs for TheraScreen® K-RAS products and is currently in a significant backorder situation. Additionally, DxS is unable to provide a TheraScreen® EGFR29 Product that meets the specifications outlined in the Distributor Agreement as the Product does not currently include the T790M mutation. Nonetheless, Roche has indicated its willingness to distribute the DxS EGFR 28 assay for the ABI platform until an EGFR-29 product is available.

46. On January 15, 2010, DxS purported to notify Roche that if the parties could not reach a resolution of the dispute by February 15, 2010, DxS would terminate the contract.

VI. Irreparable Harm Will Result If DxS is Allowed to Terminate the Distributor Agreement

47. Roche will be immediately and irreparably injured if the Distributor Agreement is terminated. Personalized healthcare is a new and emerging field. Currently, Roche is the exclusive distributor of DxS's K-RAS and EGFR tests, which are pioneer products in this relatively new market. Upon information and belief, there are no other comparable substitutes in the marketplace for the K-RAS and EGFR test kits. If DxS is allowed to terminate the Distributor Agreement, Roche will be unable to supply K-RAS and EGFR test kits, paving the way for DxS and Qiagen to take over the customer relationships that Roche has developed since May 2008 by way of its performance under the Distribution Agreement.

48. As the personalized healthcare market evolves and emerges, this is a critical time and speed is of the essence. Companies that can establish themselves in the next few years will have a unique advantage in product profile, competitive offerings and marketplace credibility. During this period, there will be great volatility as different players and technologies materialize. Having the DxS assays in its portfolio of offerings today provides Roche with an important competitive advantage. Losing that unique opportunity puts Roche at a significant competitive disadvantage, while maintaining that offering allows Roche to gain momentum during this critical market period. It is for these reasons that Qiagen paid a premium price to acquire DxS.

49. In undertaking the relief sought in this action, Roche simply seeks to maintain the status quo and to continue to perform on the Distributor Agreement through the conclusion of its term in three and a half years. For over a year, DxS has been making and delivering product to Roche. In turn, Roche has been paying for that

product. That is the status quo, and that is what Roche seeks to preserve. If the status quo is not preserved, Roche will be irreparably harmed.

50. In addition to the loss of a unique opportunity, a wrongful termination by DxS will irreparably harm Roche through a loss of goodwill and damage to its reputation. Roche is known for its exceptional products, its ability to supply those products to meet customer needs, and its excellent customer service and responsiveness. Currently, Roche has a network of customers who are expecting it to provide the DxS K-RAS and EGFR test kits. If DxS terminates the Distributor Agreement, Roche will no longer be able to supply those products to its customers, causing harm to Roche's reputation as a world-class supplier of diagnostics products.

51. Roche has agreed not to sell a competing product while the Distributor Agreement is in force. Although Roche had previously been developing products that would have been comparable to the DxS products, it had not taken steps to fully develop these products in reliance on a firm commitment by DxS to provide the products and relevant intellectual property rights for a fixed period of time. Even if Roche obtains the required intellectual property rights, it would still take Roche between 18 to 24 months to develop a competing product and then a comparable time period to bring the product to market. In the meantime, Roche will be unable to supply its customers with products (that it had promised to supply) and will likely lose those customers to Qiagen.

COUNT I
(Declaratory Judgment that Roche Did Not Breach)

52. Paragraphs 1 through 51 are incorporated herein by reference.

53. The Distributor Agreement between Roche and DxS is valid and enforceable.

54. There is an actual and justiciable controversy between the parties as to whether Roche has breached the Distributor Agreement.

55. The Distributor Agreement does not require Roche to develop software or to collaborate with DxS on software or clinical trials.

56. Roche has not breached the Distributor Agreement.

57. Roche is entitled to a declaratory judgment that it has not breached the Distributor Agreement.

COUNT II
(Declaratory Judgment that Roche Did Not Breach
the Implied Covenant of Good Faith and Fair Dealing)

58. Paragraphs 1 through 57 are incorporated herein by reference.

59. The Distributor Agreement between Roche and DxS is valid and enforceable.

60. There is an actual and justiciable controversy between the parties as to whether Roche has breached the duty of good faith and fair dealing implied in the Distributor Agreement. This includes written threats by DxS to terminate the Distributor Agreement.

61. The Distributor Agreement does not contain any provisions which require Roche to develop software or to collaborate with DxS on software or clinical trials.

62. There was no expectation by the parties that the Distributor Agreement required Roche to develop software or to collaborate with DxS on software or clinical trials.

63. Roche has not breached the implied covenant of good faith and fair dealing.

64. Roche is entitled to a declaratory judgment that it has not breached the Distributor Agreement or the implied covenant of good faith and fair dealing.

COUNT III
(Anticipatory Breach of Contract)

65. Paragraphs 1 through 64 are incorporated herein by reference.

66. The Distributor Agreement between Roche and DxS is valid and enforceable.

67. There is an actual and justiciable controversy between the parties as to whether DxS has anticipatorily breached the Distributor Agreement.

68. DxS has anticipatorily breached the Distributor Agreement by threatening to terminate the Distributor Agreement without any legitimate basis.

69. Roche will suffer harm, including irreparable harm, as a result of DxS's breach.

70. Roche will continue to suffer harm, including irreparable harm, unless DxS is enjoined from terminating the contract.

COUNT IV
(Breach of Covenant)

71. Paragraphs 1-70 are incorporated herein by reference.

72. The Distributor Agreement between Roche and DxS is valid and subsisting.

73. The Distributor Agreement is subject to an implied covenant of good faith and fair dealing.

74. DxS breached the implied covenant of good faith and fair dealing by threatening to terminate the Distributor Agreement without any legitimate basis unless Roche agreed to terms not present in the Distributor Agreement.

75. Roche has suffered harm as a result of DxS's breach of the implied covenant of good faith and fair dealing.

PRAYER FOR RELIEF

WHEREFORE, Roche prays that this Court grant the following relief:

1. Enter judgment in favor of Roche on all of its claims;
2. Adjudge that Roche did not breach the Distributor Agreement;
3. Adjudge that Roche did not breach the implied covenant of good faith and fair dealing
4. Adjudge that DxS anticipatorily breached the Distributor Agreement;
5. Adjudge that DxS breached the implied covenant of good faith and fair dealing;
6. Preliminarily and permanently restrain DxS from terminating the Distributor Agreement;
7. Preliminarily and permanently restrain DxS from selling the approved Products in the defined Territory to any entity or person other than Roche during the term of the Distributor Agreement;

8. Preliminarily and permanently restrain DxS from ceasing to supply approved Products as they are available and ordered by Roche pursuant to the Distributor Agreement;

9. Award Roche its attorney fees, costs and expenses and any other further relief this Court deems just and proper.


JURY DEMAND

Plaintiff Roche requests a jury on all issues so triable.

Dated: February 11, 2010

Respectfully submitted,

WILMER CUTLER PICKERING
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EXHIBIT A

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Welcome

DxS Companion Diagnostic Programme

DxS is a personalised medicine company that designs, develops, manufactures and sells companion diagnostic products to predict drug response in the field of cancer and other diseases. The company works in partnership with pharmaceutical companies to develop companion diagnostics to support the sale of the drug therapies to patients most likely to benefit.

Building on their experience of bringing the world's first cancer mutation companion diagnostic to market for Amgen's Vectibix drug, DxS has developed a comprehensive Companion Diagnostic Programme:



1. Biomarker Analysis Service:

DxS has a certified reference laboratory offering a portfolio of gene analysis services for use on blood and tissue samples collected during clinical development. DxS has a range of assays available including cancer mutation tests, drug metabolism polymorphisms and the custom development of new assays for a specific drug study. DxS ensures that the pharmacogenetic data produced for client studies will meet the regulatory requirements when filing regulatory submissions.

2. Validated Biomarker Products:

DxS has a range of validated biomarker products that has been developed to detect mutations in key genes. The kits are Research Use Only (RUO) tools that can be used by the pharmaceutical industry during clinical development. DxS currently has these RUO assays available for detecting the following biomarkers; K-RAS, EGFR, B-RAF, P13K and T3151 BCR-ABL. DxS has a healthy pipeline of new assays in development, however, assays can be custom developed specifically for a biomarker of interest that relates to a new therapy.

Should a clinical correlation be established DxS will work with the drug company to make a companion diagnostic available.

3. Sponsored Regulatory Approval:

DxS will work alongside the drug company and the relevant regulatory authorities to ensure that the test is approved as a companion diagnostic to support the sales of the drug in the relevant territories.

DxS has built a network of relationships with key regulatory bodies and will lead on submitting the regulatory filings.

4. Companion Diagnostics:

Once the test has been made available by the regulatory body the companion diagnostic can be launched to support the drug sale. DxS have their own manufacturing facility so the kits are designed, developed and manufactured within DxS. Roche Diagnostics is DxS' worldwide exclusive distributor for the TheraScreen®: K-RAS Mutation Kit ("K-RAS Kit"), and the TheraScreen®: EGFR29 Mutation Kit ("EGFR Kit") later in the year.


TheraScreen is the DxS brand of companion diagnostic products.

Benefits of using DxS as Companion Diagnostic Partner:

- **Accessibility** - DxS has a global distribution partner – Roche Diagnostics – to guarantee that the test is available for sale and supported in all relevant markets, leveraging Roche Diagnostics distribution channels with direct operations in 76 countries. The test will be readily available to clinicians at the time of launch to support rapid clinical uptake. Roche and DxS together take responsibility for the promotion of the companion diagnostic to pathologists and clinicians to encourage uptake of the assay for the use of the therapy.
- **Experience** –DxS has experience working with drug companies and regulatory bodies to develop a companion diagnostic and gain regulatory approval. A dedicated project team will be provided for each companion diagnostics programme.
- **Independence** – DxS is an independent company that works with different pharmaceutical companies for separate companion diagnostic programmes. DxS ensures strict confidentiality with its partners.
- **Capacity** – DxS has flexible options to meet any client needs. DxS design, develop and manufacture the products and are not reliant on third party manufacturing facilities, ensuring a smooth cross-over from validated biomarker test to approved companion diagnostic.
- **IP** – ARMS and Scorpions technology provide freedom to operate in the clinical diagnostic markets. All necessary gene licenses will be respected for each companion diagnostic.
- **Technical** - DxS technologies used in the companion diagnostic and validated biomarker test utilise a reliable and robust combination of Scorpions and ARMS technologies which are ideally suited to biomarker development.

For further information about working with DxS to develop a companion diagnostic please contact us on +44 (0) 161 204 1100 or email sales@dxsdiagnostics.com

EXHIBIT B



Sample & Assay Technologies

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QIAGEN Acquires DxS Ltd – Creating Leadership in Personalized Healthcare

In addition, QIAGEN unveils for the first time its companion diagnostic pipeline, which the Company believes is unmatched in terms of depth and profile

VENLO, The Netherlands, September 22, 2009 - QIAGEN N.V. (NASDAQ: QGEN; Frankfurt, Prime Standard: QIA) today announced that it has acquired DxS Ltd (DxS), a privately-held developer and manufacturer of companion diagnostic products headquartered in Manchester, United Kingdom. The transaction is valued at approximately US\$ 95 million in cash (subject to customary purchase price adjustments), plus up to an additional US\$ 35 million if specified commercial and other milestones are met.

With this acquisition, QIAGEN has taken a strong leadership position in the new era of personalized healthcare (PHC). The Company believes it offers all the required elements to help drive and shape this rapidly emerging trend in healthcare.

In addition, QIAGEN unveiled for the first time that the combined company is currently active in over 15 collaborations with pharmaceutical companies to market and / or develop companion diagnostic products. The programs span genetic, expression, epigenetic and other markers. QIAGEN believes that this pipeline is the deepest such portfolio in the pivotal field of molecular diagnostics for personalized healthcare.

Acquisition of DxS

The acquisition of DxS brings to QIAGEN a portfolio of molecular diagnostic assays and intellectual property, as well as a deep pipeline of active or planned companion diagnostic partnerships in oncology with many of the leading pharmaceutical companies, including seven of the largest drug makers in this field. These assets complement QIAGEN's existing strong portfolio of personalized healthcare diagnostic solutions and are very synergistic with QIAGEN's sample and assay technologies.

DxS has developed a set of molecular diagnostic assays which allow physicians in oncology to predict patients' responses to certain treatments in order to make cancer therapies more effective and safer. The currently marketed portfolio spans seven real-time PCR tests including a test for the mutation status of the oncogene K-RAS, which is indicative for successful treatment of patients suffering from metastatic colorectal cancer (mCRC) with EGFR inhibitors. In addition, three assays are in the near-term pipeline and further assays are in the medium-term pipeline. DxS' portfolio of assays, both marketed and in its pipeline, is strongly suitable for use with QIAGEN's existing suite of platform instruments, including *QIASymphony* and *Rotor-Gene Q*.

DxS is one of the pioneers which have brought molecular companion diagnostics to market. The *TheraScreen: K-RAS Mutation Kit®* developed by DxS has already been CE-marked. In the United States, the test is expected to be submitted to the FDA for regulatory approval (PMA) in 2010. It is estimated that in the future the market for overall K-RAS testing could reach up to US\$ 100 million. DxS' current portfolio and near-term pipeline includes ten unique and proprietary assays. The company has accumulated a significant intellectual property portfolio for its current and planned diagnostic content.

"The acquisition of DxS is strategically a highly important transaction for QIAGEN. It combines two leadership positions to create a very powerful leader in a transformational area of healthcare: personalized healthcare. This transaction is a key element of our strategy to lead in molecular diagnostic-based prevention, profiling and personalized healthcare. These three elements are expected to significantly shape and contribute to future improvements in healthcare and have the potential to provide significant benefits to patients as well as exceptional value for payers, providers, and the pharmaceutical industry", said Peer M. Schatz, CEO of QIAGEN.

"QIAGEN is the ideal partner for DxS to globally roll out our assays, to take our partnerships to the next level and to take a leadership position in companion diagnostics", said Stephen Little, founder and CEO of DxS. "Unlike any other company, we believe that QIAGEN addresses the broadest range of companion diagnostic options for pharmaceutical and large biotech companies - starting from an independent sales reach over broad technology, R&D and manufacturing capabilities up to expertise in regulatory affairs and access creation to physicians and laboratories."

"This combination has the potential to create a classical win-win situation for everyone involved", said Peer Schatz. "We believe that QIAGEN can use its enhanced strategic position to leverage the opportunities in personalized healthcare: pharma customers can benefit from a stronger, independent and focused partner to better serve their special development needs, employees can benefit from enhanced career opportunities, physicians can benefit from faster access to better tools for diagnosis and treatment, and healthcare systems can benefit from the potential for increases in effective and efficient treatments. But most importantly, patients who suffer from serious diseases, such as cancer, stand to benefit significantly from these new trends in personalized healthcare, which can lead to the avoidance of unnecessary or even harmful treatments and therefore to an increase in the quality of their lives."

DxS' senior management will join QIAGEN in leading roles in the Company's rapidly expanding personalized healthcare focus area, facilitating rapid integration and focus on the further expansion of this key segment. For that purpose, QIAGEN intends to establish DxS' headquarters in Manchester as a Center of Excellence in Pharma Partnering. Given the high level of synergies, QIAGEN expects to grow the Manchester location.

Transaction Highlights

- QIAGEN believes it has taken a leadership position in molecular diagnostics for personalized healthcare, positioned to help drive and shape this rapidly emerging trend.
- QIAGEN unveils for the first time the depth of its partnered companion diagnostics pipeline and is now active in over 15 partnerships. This is believed to be one of the deepest such pipelines in the industry.
- QIAGEN expands leadership in personalized healthcare, a key pillar in the Company's strategy to focus on molecular diagnostic-based prevention, profiling, and personalized healthcare.
- QIAGEN creates a leading portfolio in companion diagnostics:
 - DxS adds seven PCR assays targeting biomarkers including K-RAS and EGFR29, which may be useful in identifying patients' response to certain cancer treatments (e.g. colon, lung cancer).
 - QIAGEN's existing portfolio already included pyrosequencing-based K-RAS, BRAF and methylation assays targeting biomarkers, as well as large numbers of gene expression and miRNA assays for discovery of future biomarkers and instrument platforms to automate these tests.
- Accretion to adjusted EPS beyond the year 2010.
- Very synergistic; minimal overlap and seamless integration expected. DxS' senior management will continue to assume leading positions in expanding QIAGEN's partnerships with pharma and biotech in companion diagnostics.

Financial Details

Under the terms of the agreement, QIAGEN acquired the entire outstanding share capital in DxS. QIAGEN expects to incur one-time charges of approximately US\$ 0.02 in EPS in the third quarter 2009 in connection with this acquisition. These charges primarily relate to consulting and advisory fees incurred in connection with the acquisition and the write-off of certain assets. In addition, based on preliminary analyses and following the streamlining of the portfolio, QIAGEN expects this

transaction to contribute approximately US\$ 6 million in sales in the remainder of 2009 and approximately US\$ 30 million in sales in 2010. On an adjusted basis excluding one-time charges, integration and restructuring costs, and amortization of acquisition related intangible assets, the acquisition is expected to be neutral to EPS in the remainder of 2009 and to be dilutive by US\$ 0.02 in 2010. Beyond 2010, it is expected that the acquisition will be accretive to adjusted EPS. Jefferies acted as exclusive financial advisors in this transaction.

About QIAGEN in Molecular Diagnostics

With a run-rate over US\$ 450 million in sales and rapid growth in this segment, QIAGEN believes it is a leader in molecular diagnostics, excluding viral load testing and blood screening.

QIAGEN has defined three segments in laboratory-based molecular diagnostics it is focusing on:

1. *Prevention*: This segment covers markers tested for in asymptomatic patients for the purpose of early disease or risk detection and in regular intervals. These assays are typically performed by laboratories in high volumes. QIAGEN's portfolio in HPV testing and, in addition, the panel of assays in development (including tests for chlamydia and gonorrhea) address the most attractive and fastest growing segments in *Prevention*. These assays can be performed on current systems and on QIAGEN's *QIAensemble* platform. This platform is expected to be launched in late 2010 in Europe and in mid 2012 in the United States and is expected to set a new standard in molecular diagnostic screening in terms of throughput and utility.
2. *Profiling*: This segment covers tests performed on symptomatic patients to create or confirm a diagnosis. The assays are mostly performed at lower throughputs, but are often of higher value per test. QIAGEN's portfolio of molecular diagnostic assays (>80) for pathogens is considered one of the broadest in the world and is used to detect and profile pathogens. This segment also includes a number of genetic and other assays.
3. *Personalized Healthcare*: QIAGEN believes that this is the most transformative area of molecular diagnostics. These assays are used to guide therapy for pre-diagnosed symptomatic patients. They are typically higher value, lower volume assays. QIAGEN today sells approximately 20 assays in personalized healthcare.

In *Personalized Healthcare* and *Profiling* throughput requirements are lower than in the segment of *Prevention*, but the bandwidth requirements (sample types, etc.) are much higher. The random access, continuous load *QIASymphony* platform (sample to result, of which the first modules have been very successfully launched) was designed for these segments.

About QIAGEN in Personalized Healthcare

QIAGEN believes it brings a special value proposition to pharmaceutical companies for companion diagnostics development projects. The Company is considered a key partner as it is:

- The largest molecular diagnostics company based on revenues, technology and portfolio breadths, outside blood screening/viral load testing.
- A significant supplier to pharmaceutical discovery and development already today.
- Owner of a broad technology portfolio in molecular sample & assay technologies.
- Independent: not owned by a pharmaceutical company.
- A company with strong regulatory presence, sales channel strength and global reach.

About Companion Diagnostics and Personalized Healthcare

Companion diagnostics are expected to become a key contributor to the transformational trend towards personalized healthcare (PHC). In addition to the increasing awareness of the significant benefits of PHC to key players in healthcare (payers, physicians, regulators, patients), new possibilities in molecular diagnostics and in particular very recent regulatory and payer decisions, most notably around products where DxS' portfolio plays a key role, have accelerated the trend towards a more integrated use of diagnostic information to guide therapy.

While most current companion diagnostics are "retrofitted" diagnostics, i.e. diagnostics that were retroactively added to approved drugs to improve outcomes, the new generation of companion diagnostics is being developed together with drugs to predict responses of patient populations to the drug treatment and increase its efficacy and safety. By testing for specific genetic variations related to certain biomarkers, health professionals can customize their therapies and avoid unnecessary or harmful treatments. The concept of personalized healthcare plays an increasingly important role in treatment decisions in clinical areas such as cardiovascular and neurological diseases and - most prominently - in cancer. There are 28 companion diagnostic tests for valid genomic biomarkers identified by the FDA in the context of FDA-approved drug labels. According to industry reports, the market for personalized healthcare grew annually at 24% over the last decade, amounting to US\$ 13 billion in 2008.

About QIAGEN:

QIAGEN N.V., a Netherlands holding company, is the leading global provider of sample and assay technologies. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are used to make such isolated biomolecules visible. QIAGEN has developed and markets more than 500 sample and assay products as well as automated solutions for such consumables. The company provides its products to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers for purposes such as forensics, animal or food testing and pharmaceutical process control. QIAGEN's assay technologies include one of the broadest panels of molecular diagnostic tests available worldwide. This panel includes the digene HPV Test, which is regarded as a "gold standard" in testing for high-risk types of human papillomavirus (HPV), the primary cause of cervical cancer, as well as a broad suite of solutions for infectious disease testing and companion diagnostics. QIAGEN employs more than 3,200 people in over 30 locations worldwide. Further information about QIAGEN can be found at <http://www.qiagen.com/>.

About DxS:

DxS is a personalized healthcare company providing molecular diagnostics to aid doctors and drug companies in selecting safe and effective therapies for patients based on their molecular profiles (Companion diagnostics). Headquartered in Manchester, UK, the company employs approximately 80 employees in two countries, most of them in the UK. More information about DxS can be found at <http://www.dxsdiagnostics.com/>.

SAFE HARBOR STATEMENT

Statements contained in this release that are not historical facts are forward-looking statements, including statements about our products, markets, strategy and operating results. Such statements are based on current expectations that involve risks and uncertainties including, but not limited to, those associated with: management of growth and international operations (including currency fluctuations and logistics), variability of our operating results, commercial development of our markets (including applied testing, clinical and academic research, proteomics, women's health/HPV testing, molecular diagnostics, personalized healthcare and companion diagnostics), our relationships with customers, suppliers and strategic partners, competition, changes in technology, fluctuations in demand, regulatory requirements, identifying, developing and producing integrated products differentiated from our competitors' products, market acceptance of our products, and integration of acquired technologies and businesses. For further information, refer to our filings with the SEC, including our latest Form 20-F. Information in this release is as of the date of the release, and we undertake no duty to update this information unless required by law.

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